House Committee on Small Business
Subcommittee on Rural and Urban Entrepreneurship

"Competitive Bidding for Durable Medical Equipment"

May 21, 2008

Testimony of Mr. Casey Hite
Vice-President, Aeroflow Healthcare
Asheville, NC

Testimony of the
American Association for Homecare
before the
Subcommittee on Rural and Urban Entrepreneurship
of the Committee on Small Business

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Good Morning Mr. Chairman and distinguished members of the Subcommittee on Rural and Urban Entrepreneurship. My name is Casey Hite. I am a small business owner and Vice-President of Aeroflow Healthcare, a small home medical equipment company in Asheville, North Carolina. I appreciate this opportunity to testify before you today, on behalf of the North Carolina Association for Medical Equipment Services (NCAMES), the American Association for Homecare (AAHomecare) and small home medical equipment providers across the nation.

Aeroflow Healthcare is a company that my brother and I founded in 2001. Aeroflow provides oxygen and mobility equipment and services to approximately 13,000 active patients in North Carolina, South Carolina and Tennessee who have respiratory and mobility-related problems. I entered the home medical equipment industry to provide compassionate care to western North Carolina's elderly and disabled population. I decided to enter this industry after visiting my grandmother who was slowly dying from chronic heart failure in a local nursing home. The nursing home was providing her with oxygen from a dilapidated oxygen concentrator that broke down frequently which caused her to have severe anxiety about potentially dying in her sleep. At that time, the only home medical equipment providers in the area were large corporations that were based in Florida or as far away as California. We believed there had to be a better way.

AAHomecare is the national trade association representing both providers of durable medical equipment and manufacturers across the nation. The Association's membership reflects a broad cross-section of the homecare community including home medical equipment (HME) providers of all sizes operating in approximately 3,000 locations in all 50 states. NCAMES is the state home medical equipment association representing 250 providers. NCAMES and AAHomecare work to strengthen access to high quality care for millions of Americans who require home medical equipment, services and therapies in their homes. Many of AAHomecare's member providers operate health care facilities and businesses in areas that are subject to the Medicare competitive bidding program. I am scheduled to be in Round Two of bidding by virtue of serving beneficiaries in the Asheville, North Carolina area and I have heard and seen in detail Round One problems that have plagued this high-profile program. I am well aware of the bidding program's anticipated effects on both Medicare beneficiaries and suppliers.

Summary

The Medicare bidding program is a poorly conceived and fundamentally flawed program that is now exhibiting many of the serious breakdowns that AAHomecare predicted based on CMS' failure to recognize and account for the true nature of the way home medical equipment is provided to Medicare beneficiaries.

The current bidding program will drive thousands of qualified HME providers out of the Medicare marketplace. One of the consequences will be limitations on services available to millions of seniors and people with disabilities. Nearly two-thirds (63 percent) of accredited, qualified homecare providers that submitted bids have been disqualified in the first round of bidding. Such a dramatic reduction in the number of homecare facilities will result in reduced access to home medical equipment providers and the quality of services that they provide if this bidding program moves forward in its current form.

This program will eliminate thousands of qualified providers, reduce services to beneficiaries, and systematically dismantle the nation's homecare infrastructure. HME providers are overwhelmingly small to mid-sized practices that typically receive about 40-50 percent of their business from Medicare patients. The loss in the ability to serve this patient population will result in layoffs and many business failures. The term "competitive bidding" is misleading because CMS is radically reducing the number of suppliers that compete in a given area resulting in market concentration rather than a competitive marketplace.

The changes that will result from the bidding program will affect over three million beneficiaries who reside in Round One areas. CMS has indicated that if Round Two is implemented, approximately 18 million, or about half of all Medicare beneficiaries requiring home medical equipment could be affected, that is as many as eighteen million beneficiaries. The bidding program could also quickly affect all Medicare beneficiaries in the U.S. as early as January 1, 2009, when CMS will have the authority to apply bid pricing in non-bidding areas. The ability of CMS to apply bid pricing to non-bidding areas, especially rural areas with hard-to-reach patients, is clearly not market-based.

Congress must not let this program move forward, in its current form. We urge you to delay the implementation of this program until the wide range of problems and questions about the program can be independently evaluated and an alternative process to determine payment rates for home medical equipment can be explored. Without a delay in the implementation timeline to review serious concerns and examine alternatives, Medicare's home medical equipment benefit will be irreparably harmed.

Bidding Implementation Problems

The Medicare bidding program is expected to immediately impact more than 4,500 home medical equipment companies in the first ten metropolitan statistical areas. Ultimately, only 1,005 unique supplier companies submitted bids to CMS for consideration. Of that, 630 supplier companies were disqualified from consideration because of a failure to submit complete and accurate information—leaving a pool of only 375 companies for CMS to consider. We do not believe that any program where more than 60 percent of suppliers were disqualified should be considered a success. These statistics point to a failure by CMS to educate suppliers properly about the bidding program and flaws within the internal bid submissions review process.

The lack of supplier participation can be traced back to the initial bid submission period in May 2007. Suppliers in the 10 metropolitan areas subject to bidding immediately encountered a wide range of significant problems.

Suppliers found that the bid submission system was primitive, cumbersome and fraught with problems resulting in excessive data input time and loss of submitted data. Frequently, the system was non-operational and inaccessible.

The problems faced by suppliers during the bidding window were so significant that CMS extended the bidding window three times (two one-week delays followed by a 60-day delay) which we believe led to some suppliers being unable to navigate the program and therefore fully participate in it.

More procedural and operational flaws that threatened the integrity of the entire program became more readily apparent when CMS began informing suppliers of whether they won a contract on March 21. These flaws include, among others: (1) the Competitive Bidding Implementation Contractor's (CBIC) inappropriate rejection of qualified bids due to misplaced or overlooked documentation that was submitted by suppliers properly and in a timely manner; (2) inappropriate disqualification of bids due to purported "financial stability" reasons, which neither the CBIC nor CMS has ever explained during or after the bidding process; (3) a seemingly arbitrary process regarding how the CBIC or CMS used providers' self-reporting capacity to determine how many winning suppliers were needed for each market; and (4) extremely minimal information disclosed in terms of the calculation of the winning bid amounts and related results.

The original "request for bids" rules on the CBIC's website stated that the CBIC would inform suppliers of any deficient documentation; the original RFB rules said that, "beginning 10 business days before the bidding window ends, suppliers will be notified if there is any missing hard copy attachments." These rules were in place as of May 2007, and were observed by suppliers as they navigated the cumbersome and confusing bid process. However, on September 13 (just prior to the closing date of (Sept. 25, 2007), the CBIC revised this RFB rule without any notice to the bidding community.

Equally troubling, especially in light of an extraordinary disqualification rate of 63 percent, is that CMS has never delineated a process at any time in the development or implementation of this program by which suppliers who were disqualified would be able to have their cases reviewed. Subsequent to the mass disqualification of suppliers on March 21, the CBIC initially informed suppliers who questioned their disqualification that their cases would be reviewed for accuracy within 30 days. The CBIC reneged on this promise sending e-mail communication to some of these suppliers indicating that it would not be able to meet its stated review period. For others, the CBIC has just reaffirmed the original "incorrect" disqualification and left these suppliers, who have proof that they have been wrongly disqualified, with no avenue for a proper review of their supporting information.

Home Medical Equipment Supplier Impact

We believe that the Medicare bidding program will radically change the HME marketplace and dismantle the nation's home medical infrastructure if implemented in its current form. CMS will selectively contract with approximately only 300 unique supplier companies in the first 10 metropolitan areas under the fee-for-service program. CMS' own statistics have shown that approximately 4,500 unique companies reside in these 10 bidding areas. This would indicate that CMS intends to contract with approximately 7 percent of existing home medical equipment companies. Even if we only account for the unique companies that took part in the program—1,005

companies—CMS is still threatening the financial viability of 70 percent of the otherwise qualified and accredited suppliers in the current homecare marketplace.

The integrity of contract suppliers may also become a question since some suppliers who participated in the program submitted bids based on the assumption that they would be awarded contracts for multiple product categories subject to bidding. If, for example, a supplier submitted its bids expecting to be a contract supplier for multiple product categories but only "won" a contract for one product category, the supplier's long-term sustainability may be in question.

Homecare has been shown to be the most cost-effective and patient-preferred type of care provided to beneficiaries. As baby boomers retire and become eligible for the Medicare program, demand for home medical equipment is likely to increase. These beneficiaries will prefer the advancements in technology that allow them to live full lives in the home setting. Arbitrarily limiting the number of homecare companies that the market will support should be viewed as selective contracting, not competitive bidding.

Savings Questionable

The bidding program designed by CMS is fatally flawed and its widely touted savings are misleading. Smaller suppliers were fearful that larger suppliers had a competitive advantage in the bidding system due to the ability of these larger suppliers to negotiate volume pricing with manufacturers. As a result, smaller suppliers believed they could only remain viable by bidding at levels that were extraordinarily low, but assumed that larger supplier bids would reflect accurate (higher) pricing and would increase the final Medicare single payment amount, thus, rationalizing payments.

Essentially, small suppliers bid unreasonably low to have an opportunity to "stay in the game" since the alternative was to risk business failure immediately. The fact that a large percentage of suppliers offered contracts, 63 percent, were small suppliers validates this theory. Because so many small suppliers bid so low, these bidders came close to meeting the capacity projections; preventing many of the larger firms' bids from being incorporated into the matrix of pricing. We believe the extraordinarily low bid rates will be unsustainable over a three-year contracting period.

The argument that the pricing levels established through bidding are indicative of market pricing is unfounded. The bid system established an elaborate "game" with skewed incentives, resulting in prices that are not reflective of market pricing; but instead were based upon a desperate need to "stay alive" through the bid program.

We anticipate that beneficiaries in the bid areas will receive lesser quality items and reduced services. Also problematic will be beneficiary disruption and confusion that will lead to additional program costs in the form of longer hospital stays, more frequent physician visits and care sought in emergency rooms. None of these factors has ever been identified by CMS in its presentation of savings that can be achieved through bidding.

Lack of Government Transparency

The development and implementation of the bidding program have been shrouded in secrecy. All businesses rely on transparency and clear rules in order to operate effectively. For small businesses, in particular, this is especially critical. The lack of transparency masks deficiencies of the program and makes it impossible to evaluate fully the way CMS reached its various decisions at every stage of the process as well as how small businesses were expected to compete. CMS' unwillingness to share basic

information about the program raises serious questions about any future rounds with respect to fair supplier selection and patient access to quality suppliers. Their guidance to the supplier community has also been inadequate with an unrealistic timeline and processes to accommodate any transition.

CMS has not shared meaningful bidding data, the methodology and criteria used to establish new Medicare payment rates or the criteria by which suppliers were evaluated. By refusing to release critical data, CMS is impeding an open assessment and dialogue with the public.

How did CMS evaluate the financial stability of providers? How did CMS review a supplier's self-reporting capacity to meet market need? Did CMS properly calculate the single payment amount? What criteria did CMS use to evaluate bids and determine whether a bid was a "bone fide" one? What process did CMS use to reevaluate the bidding packages of suppliers who believe they were inappropriately disqualified from the program? These and other questions still remain unanswered and threaten the integrity of the bidding program.

Consequences of Bidding

Impact on Beneficiary Quality of Care

Many Medicare beneficiaries who reside in bidding areas will likely see: (1) a reduction in the level of services they receive; (2) lower quality items that may not be tailored to their specific needs; and, (3) disruptions in continuity of care as they are forced to switch providers.

Under the bidding program, suppliers are required to provide the same products to Medicare beneficiaries as they provide to non-Medicare patients, but only in situations where a physician specifically prescribes a certain product and brand. In all other cases, suppliers have the option to provide a range of products that fit within the physician's prescription. With the drastic reduction in reimbursement rates, there will be a diminution in the quality of goods and the level of service that suppliers have furnished in the past.

Additionally, CMS has also awarded contracts to suppliers who currently have no physical presence in bidding areas. These suppliers have the following options: they can: (1) quickly form subcontracting arrangements with local suppliers, or (2) attempt to open a new location(s) to service beneficiaries residing within a bidding area. In either case, suppliers will have to make these changes in the next 27 business days because the program starts on July 1.

In the complex power wheelchair marketplace, there are a number of troublesome areas that will impact quality of care. A contract winner who is not currently located in the bidding area could attempt to form subcontracting arrangements. However, the Medicare allowable set through bidding is unlikely to financially support both the contract supplier and the subcontractor. Also, CMS accrediting bodies cannot guarantee that "winning" suppliers exclusively use accredited subcontractors. In its final rule on bidding, CMS stated that it will "not evaluate subcontractors to determine if they meet the accreditation, quality, financial and eligibility standards because a subcontractor to a contract supplier cannot itself be a contract supplier and cannot submit claims under the Medicare DMEPOS Competitive Bidding Program." Moreover, these subcontracting

suppliers could provide the beneficiary with a very inexpensive power wheelchair system that may not be as durable as the complex power wheelchairs that are currently provided nor meet all of the beneficiary's needs. Finally, CMS does not mandate that suppliers repair the complex power wheelchair they provide. Given the low payment rates for repairs, the Medicare beneficiary may very likely find him/herself unable to find a provider willing to repair the power wheelchair.

In the diabetic arena, CMS made decisions that are likely to jeopardize disease management services to Medicare beneficiaries. In the diabetes treatment area, CMS did not ensure that all bidders played by the same rules. First, it did not define a formulary and it did not apply the rules of bidding equally to all bidders. As a result, CMS may have significantly limited beneficiaries' range of choices of diabetes monitoring systems and supplies. Second, by excluding retail providers from the bidding process, CMS distorted and clearly undermined the objectives of competitive bidding by allowing more than one reimbursement rate for the same product in a competitive bidding area. This was not envisioned by Congress. This policy is anti-competitive. Unless winning suppliers are providing the same or equivalent products or services as are provided today, patients may now turn to retail stores for their supplies, where the cost is greater and where there are no Medicare savings. We believe that CMS should establish one reimbursement rate for a product in a bidding area regardless of where it is purchased, at a fair rate that allows choice so that beneficiaries do not have to switch their products and systems.

Prior to bidding being implemented, significant policy changes have been slated to take effect that will impact home oxygen beneficiaries. The transfer of ownership of oxygen equipment and the 36-month payment cap—which both go into effect on January 1, 2009— are very likely to cause confusion with beneficiaries and adversely impact the level and quality of service beneficiaries have come to expect. These issues will only be magnified with bidding and its additional set of rules. For example, a beneficiary who is in his/her 31st month on oxygen therapy with an advanced oxygen system and who moves to a new geographic area is unlikely to find an oxygen provider willing to furnish him or her with the same level of technology.

There is also the real issue of suppliers being unable to ramp up operations to meet significant new demand for medical equipment and services subject to bidding. While CMS has presumably selected enough suppliers to service an entire bidding area for each product category, contract suppliers must prepare for a significant increase in demand for these items and services. Based on the information provided by CMS that identifies the number of contracts that were offered in each product category and each bidding area, contract suppliers could see an increase of 200-300 percent in the number of patients they are required to serve. Suppliers may be overwhelmed by the huge increase in volume, which their systems and infrastructure did not anticipate or may not be able to handle. This is especially true for suppliers who have never operated in bidding marketplaces prior to the implementation of this program. Contract suppliers that cannot meet demand are unlikely to provide the level of service to which patients are accustomed.

My overarching concern with the bidding program is that I can foresee a decline in the quality of equipment and service when beneficiaries change products to generic or less costly items. Beneficiaries will be forced to switch providers with whom they have had a trusted relationship for years. Imagine a child growing up with a disability through to

adulthood who has been using one HME provider his or her entire life, and now, as an adult under the bidding program, must switch to a new provider who is unfamiliar with his or her medical history or specific needs. Items such as oxygen services for a person living with COPD or a customized power wheelchair for a person living with ALS, are not luxury items that consumers are able to live without but instead are essential life-sustaining items and services.

The cost of the medical equipment that we provide is only a fraction of the total cost of caring for a patient. There are additional costs associated with hiring employees, training staff to file insurance claims, training and having licensed therapists on staff, and the costs associated with meeting various federal and state licensing requirements. Suppliers must consider these additional business costs as they evaluate their bids under the competitive bidding program. My company may not be able to continue to provide items and services if we are not a contract supplier and must consider grandfathering patients at the winning bid rate.

As this untested program begins, we must be aware of the enormous real-life impact that this program will have on individuals with significant disabilities such as spinal cord injuries, cerebral palsy, multiple sclerosis and ALS.

Impact on Beneficiary Access to Care

Few beneficiaries are aware that changes resulting from this program are imminent. If services and quality are reduced, if access is curtailed or beneficiary compliance diminishes—all likely outcomes from this program—Medicare costs will increase as patients require longer hospital stays, seek more frequent physician interaction and visit the emergency room.

We are aware of some suppliers that were awarded contracts for certain product categories, which those same suppliers never before provided. In these circumstances, CMS has never outlined how it evaluated a supplier's self-reported plans to provide these new services. We also question how these suppliers could submit accurate bids for such services and items while also incorporating an unknown demand factor and operation costs into their bid calculation.

Consider the range of beneficiaries that will be impacted by bidding effective July 1:

• More than 220,000 Medicare beneficiaries who currently rely on home oxygen therapy may experience a disruption of their service if their provider does not elect to "grandfather" existing patients, and tens of thousands of new patients prescribed the therapy will have severely limited access from July 1, 2008 forward. As these beneficiaries assume ownership of their equipment in January 2009, they may have to switch providers in order to obtain portable oxygen.

• 143,000 beneficiaries currently receiving home-delivered diabetic supplies may be forced to switch providers by July 1 since there is no "grandfathering" provision. Small "winners" will likely be overwhelmed by the rush of patients switching suppliers by CMS' deadline.

• 10,000 beneficiaries currently receiving home enteral nutrition therapy may be forced to switch providers by July since there is no "grandfathering" provision.

• 16,000 beneficiaries currently being treated at home for Obstructive Sleep Apnea (OSA) may have to switch providers as they assume ownership of their equipment under the Deficit Reduction Act (DRA).

• 25,000 elderly beneficiaries currently relying on hospital beds to remain at home may have to switch if their providers do not "grandfather" due to pricing in one or more markets.

Beneficiaries are also likely to face the prospect of coordinating care with multiple suppliers in bidding areas. Prior to bidding, a beneficiary's home medical equipment needs could be served by one supplier. Now, suppliers can only serve beneficiaries for items and services subject to bidding for which they have received a contract. If a beneficiary needs a hospital bed, a walker and oxygen therapy, the beneficiary may require care from three separate suppliers due to the mechanics of the bidding program.

Home visits are an important part of the quality service that AAHomecare members provide to their customers, including Medicare beneficiaries, many of whom are homebound. Most Medicare beneficiaries who require power wheelchairs live with long-term debilitating conditions that are not short-term in nature and, with few exceptions, use a power wheelchair for the remainder of their lives. Medicare beneficiaries who require access to appropriate mobility devices rely on their wheelchairs in order to maintain their independence and quality of life. If the new contract provider cannot afford to provide home visits, that consumer must rely on others to drive him or her to the new provider. That new provider may be great distances away.

Failure to Educate Beneficiaries, Referring Clinicians and Suppliers

CMS has touted an extensive list of steps it has taken to educate the supplier community about competitive bidding. Nevertheless, 63 percent of suppliers who attempted to participate were unable to navigate the bidding process and operational questions remain. Further, the supplier community, who has the most direct contact with existing beneficiaries that will be impacted by this program, has never been formally engaged by CMS to educate the beneficiary community on the changes that will result from bidding. To our knowledge, CMS has published only one pamphlet, in October 2007, to educate Medicare beneficiaries. This is for a program that is scheduled to go into effect in 27 business days.

Now that there are "winners" and "losers" because of the program, "losing" suppliers have no incentive to educate beneficiaries and "winning" suppliers are consumed with the prospect of ramping up their operations to handle a significant increase in demand for services.

Once again it is the beneficiary who will suffer. Unfortunately, ensuring that three million beneficiaries in the 10 areas subject to bidding are educated on how the home medical equipment benefit will operate will be extremely difficult in the remaining days before this program goes into effect. Many Medicare beneficiaries who rely on or will need home medical equipment and services are the most frail within our health care system. Many do not have access to the internet. They are homebound. They are not able to attend public meetings like those held to educate beneficiaries about the Medicare Part D program.

Recommendations

Due to the flaws, errors and questions that have plagued Round One, and will certainly carry through to Round Two, we urge Congress to delay the implementation of this bidding program. We support the implementation of a rational, alternative process to determine Medicare pricing for DME items and services. AAHomecare stands ready to work with members of this Subcommittee and other members of Congress to address these complex challenges and ensure the provision of cost-effective and quality homecare to deserving Medicare beneficiaries.